1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

MYLERAN film-coated tablets

Busulfan 2 mg

Contains sugar: Lactose anhydrous 92,5 mg

Read all of this leaflet carefully before you start taking MYLERAN because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- MYLERAN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What MYLERAN is and what it is used for

MYLERAN contains the active substance busulfan which is called a cytotoxic medicine (also called chemotherapy). MYLERAN is used for certain blood problems and cancers of the blood. It works by reducing the number of new blood cells your body makes.

MYLERAN is used for

- Chronic myeloid leukaemia - A disease that increases the number of white blood cells. This can cause infections and bleeding.

You must talk to a doctor if you do not feel better or if you feel worse after a few days.

2. What you need to know before you take MYLERAN

Do not take MYLERAN

- If you are hypersensitive (allergic) to busulfan or any of the other ingredients of MYLERAN (listed in section 6).
- If you have taken MYLERAN before and it did not work.
- If you have been recently vaccinated, or plan to be vaccinated with a live vaccine.
- If you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with using MYLERAN

- as MYLERAN is an active cytotoxic medicine for use only under the direction of medical practitioners experienced in the administration of such medicines.
- if you have been recently vaccinated, or plan to be vaccinated with a live vaccine, as it can make your body less able to fight infections.

- if you experience shortness of breath or lung disease which could be due to scarring and thickening in the lungs such as pulmonary fibrosis, interstitial pneumonia or lung toxicity.
- if you have a lung disease and have had or may require anaesthesia.
- if you have had radiotherapy or chemotherapy, now or recently.
- if you have a liver or kidney problem.
- if you have ever had gout (painful and swollen joints caused by uric acid crystals). You may need treatment for your gout before you start taking MYLERAN.
- if you have an inherited blood problem called thalassaemia.
- if you experience dark patches on your skin (hyperpigmentation).
- if you experience the following symptoms: weakness, severe tiredness, anorexia, weight loss, nausea and vomiting and hyperpigmentation of the skin which may be symptoms of clinical syndrome resembling adrenal insufficiency (Addison's disease).
- if you experience the following symptoms: tiredness, fever, infection and bruising which may be symptoms of a secondary blood cancer. It is possible that the use of MYLERAN, particularly long term use, may increase the risk of developing a secondary blood cancer. In many cases, patients who develop this have also received another type of chemotherapy or some form of radiation therapy. Tell your doctor as soon as possible if you have any of these symptoms.
- if you suffer from porphyria (an inherited disorder of blood pigment metabolism).
- if you are taking medicine to treat fungal infections (ketoconazole, itraconazole or metronidazole).
- as MYLERAN may cause the formation of malignant tumours which are cancer cells or abnormal cells which divide uncontrollably and destroy body tissue.
- as abnormal cell changes may occur during the use of MYLERAN. These changes will need to be monitored by your healthcare provider.
- as MYLERAN may cause changes to genetic material, such as DNA.

- as MYLERAN can disturb development of the unborn baby.
- as MYLERAN may cause sterility in men and women. You should speak to your healthcare provider before you start treatment with MYLERAN.

Other medicines and MYLERAN

Tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

- Other cytotoxic medications used for cancer treatment (chemotherapy) - when used with MYLERAN as there is a greater chance of side effects, such as breathing problems, especially in children as this may lead to toxicities (see section 4).
- Thioguanine (used to treat certain cancers) as they may cause liver toxicity.
- Phenytoin (used to treat and prevent fits) - your doctor may need to change your phenytoin to a different medicine.
- Vaccines which contain live organisms (such as oral polio, measles, mumps and rubella) - MYLERAN can make your body less able to fight infections.
- Itraconazole (used for fungal infections) or metronidazole (used for bacterial infections) - they can cause serious side effects if used with MYLERAN (see section 4).
- Cyclophosphamide (used for certain types of blood disorders) - if used with MYLERAN, it is best that your first cyclophosphamide dose is given 24 hours or longer after the last MYLERAN dose. This will reduce the chance of any possible side effects.
- An anaesthetic for an operation at the hospital or dentist.
- Paracetamol use during MYLERAN administration should be used with caution.

Pregnancy, breastfeeding and fertility

You should not take MYLERAN if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby please consult your healthcare provider for advice before taking MYLERAN.

Driving and using machines

MYLERAN has moderate influence on the ability to drive and use machines. Since adverse reactions such as fits and eye disorders have been reported in patients receiving MYLERAN (see section 4), you should not drive, use machinery or perform any tasks that require concentration, until you are certain that MYLERAN does not adversely affect your ability to do so.

MYLERAN contains lactose anhydrous

MYLERAN contains lactose anhydrous which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take MYLERAN.

3. How to take MYLERAN

Do not share medicines prescribed for you with any other person.

Always take MYLERAN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of MYLERAN depends on the type of your blood problem or cancer. Your doctor may change your dose during your treatment depending on your needs.

The dose can sometimes be changed if you are over-weight.

When you take MYLERAN your doctor will take regular blood tests to check the number of cells in your blood and your medicine dose may be adjusted as a result.

MYLERAN is administrated orally.

Swallow your tablets whole with a glass of water. Do not break, crush or chew the tablets.

If you have the impression that the effect of MYLERAN is too strong or too weak, tell your doctor or pharmacist.

If you take more MYLERAN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take MYLERAN

Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

MYLERAN can have side effects.

Not all side effects reported for MYLERAN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MYLERAN, please consult your healthcare provider for advice.

If any of the following happens, stop taking MYLERAN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MYLERAN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- an increased risk of developing a secondary blood cancer (leukaemia),
- your heart might not be able to beat properly (cardiac tamponade), especially in patients with an inherited blood problem called thalassaemia,
- shortness of breath, difficulty or laboured breathing (dyspnoea), inflammation of the lungs which cause breathlessness, cough and increased temperature, or inflammation of the lungs with no sign of infection (called idiopathic pneumonia syndrome), cyanosis (a bluish discoloration of the skin due to poor circulation) or inadequate oxygenation of the blood (hypoxia), orthopnoea (the inability to breathe easily unless the person is sitting up straight or standing erect) (pulmonary fibrosis,
- any unexpected bruising or bleeding, as this could mean that too few blood cells of a particular type are being produced (bone marrow depression, leukopaenia or thrombocytopenia),
- a severe drop in red blood cells which can cause tiredness, weakness, bruising and make you more likely to get infections (aplastic anaemia),
- convulsions (fits or seizures) with high-dose MYLERAN,

- liver damage/problems (hepatotoxicity), including jaundice - signs include yellowing of your skin and eyes, sometimes with a fever, pale stools and dark urine,
- signs of blood in your urine and pain when passing water (bladder inflammation, haemorrhagic cystitis) – with high doses of MYLERAN at the same time as taking a medicine called cyclophosphamide,
- muscle weakness commonly leading to drooping eye lids and difficulty in speaking or using your arms and legs (myasthenia gravis),
- clouding of the normally clear lens of the eye (cataract),
- an immune system disorder characterised by dry eyes and dry mouth (Sjögren's syndrome),

These are all serious side effects. You may need urgent medical attention.

The following side effects have been reported very commonly:

- feeling sick (nausea), being sick (vomiting), diarrhoea or mouth ulcers (sores),
- enlarged liver,
- in women, periods may stop (amenorrhoea), fertility may be affected and menopause may start early (ovarian disorders),
- in girls, the start of puberty may be delayed or prevented,
- in boys and men, sperm production may be delayed, reduced or stopped and your testicles may reduce in size,
- increased bilirubin in the blood which may cause dark urine, pale-coloured stools, yellow staining of the skin and the whites of the eyes (hyperbilirubinemia)

The following side effects have been reported commonly:

- hair loss,

- appearance of patches of dark skin (hyperpigmentation)

The following side effects have been reported rarely:

- dysplasia which is the enlargement of an organ or tissue by the proliferation of cells of an abnormal type, as a developmental disorder or an early stage in the development of cancer,
- dry mouth and lips or other skin changes including very dry skin,
- eye and vision problems

The following side effects have been reported very rarely:

- enlargement of breasts in men (called gynaecomastia),
- weakness, feeling very tired, weight loss, feeling sick, and being sick – which resembles Addison's disease (but with the adrenal glands working correctly)

The following side effects have been reported with a frequency that is unknown:

- deposition of calcium in abnormal tissue (formation of a bone at an unusual location) such as scar tissue or atherosclerotic plaques, without abnormalities of blood calcium (dystrophic calcification),
- changes in the hard, protective outer layer of your teeth (tooth hypoplasia).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of MYLERAN.

5. How to store MYLERAN

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MYLERAN contains

The active substance is busulfan.

The other ingredients are lactose anhydrous, magnesium stearate, starch pregelatinised.

Tablet film coating: Opadry White OY-S-7322- which contains:

Hypromellose, titanium dioxide (C.I.77891), triacetin (glycerol triacetate).

What MYLERAN looks like and contents of the pack

MYLERAN 2 mg tablets are white, film-coated, round, biconvex tablets imprinted with “GX EF3” on one face and “m” on the other.

MYLERAN tablets are available in bottles of 25 tablets and 100 tablets

Not all packs and pack sizes are necessarily marketed.

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE APPLICANT

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

This leaflet was last revised in 5 March 2020

REGISTRATION NUMBER

MYLERAN: H2750 (Act 101/1965

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

ZA_MYLETAB_2003_00